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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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~~09/734,752~~ ~~12/11/00~~ ~~WARRINGTON~~ J 3308.3

022886 HM12/0507  
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EXAMINER

SPIEGLER, A

ART UNIT	PAPER NUMBER
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1656

DATE MAILED:

05/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/734,752

Applicant(s)

WARRINGTON ET AL.

Examiner

Alexander H. Spiegler

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-2 is indefinite over the recitation of “measuring the physiological state of said experimental sample” because it is not clear as to how one measures a physiological state of a sample.

B) Claims 1-2 are indefinite over the recitation of “similar”, which is a relative term which renders the claim indefinite. The term “similar” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

C) Claims 1-2 are indefinite over the recitation of “matches” because it is not clear as to what is matched between the experimental and reference samples.

D) Claims 3-6 are indefinite because the claims do not recite a final process step which clearly relates back to the preamble. For example, with respect to claim 3; the preamble states, that the method is for identifying markers to assay efficacy of drug therapies in women, but the final process step is for measuring the expression profile of a female sample before drug treatment, and comparing it to the expression profile of a sample from the same subject after

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drug treatment. Therefore, it is unclear as to whether the claim is intended to be limited to a method of identifying markers to assay efficacy of drug therapies in women or a method of measuring the expression profile of a female sample before drug treatment, and comparing it to the expression profile of a sample from the same subject after drug treatment.

E) Claim 4 is indefinite over the recitation of "matching indicators of physiological status" because it is not clear as to whether the experimental and reference samples have the matching indicators of physiological status or whether the plurality of reference samples have matching indicators of physiological status.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Friend et al. (USPN 6,218,122).

Friend teaches methods of monitoring disease states and therapies using gene expression profiles. Specifically, Friend teaches a method of determining (i.e. diagnosing) the level of a disease of a sample comprising; (a) obtaining a diagnostic profile (i.e. experimental sample) by measuring the abundance of cellular constituents in a cell (i.e. expression profile) from a subject known or suspected of having a disease state; (b) obtaining interpolated perturbation response profiles for each disease state being monitored by, first, obtaining response profiles by measuring

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the abundance of cellular constituents that occur in cells of an analogous subject or subjects at a plurality of levels of each disease state (i.e. reference samples of known disease states), and second, interpolating the thus obtained response profiles; and (c) determining the interpolate perturbation response profile for each disease state for which similarity is greatest between the diagnostic profile and a combination of the determined interpolated response profiles (i.e. comparing the experimental sample to the reference sample), wherein the level of a particular disease state is thereby indicated by the disease level correlated to the thus determined interpolated response profile for that disease state (i.e. diagnosing the experimental sample with the disease of the matching reference sample) (col. 3, ln. 7-26). With respect to claims 3, 7, and 9, the reference teaches methods for monitoring the beneficial effects or adverse effects of a therapy, such as drug treatment (i.e. pharmacological state) (col. 3, ln. 27-49) in human patients (i.e. woman) (col. 4, ln. 58-59). The reference further teaches that the analogous subject is a subject of the same species exhibiting the disease state, and may be of the same sex and or approximate age (i.e. physiological status) (col. 14, ln. 9-12).

5. Claim 3 is rejected under 35 U.S.C. 102(e) as being anticipated by Lockhart et al. (USPN 6,033,860)

Lockhart teaches that potential drugs can be screened to determine if the expression of particular genes is inappropriately altered (i.e. a method of identifying markers useful in gene expression) (col. 3, ln. 67 to col. 4, ln. 2). This may be useful, for example, in determining whether a particular drug is prescribed to a pregnant woman (i.e. drug therapy in a woman) (col. 4, ln. 2-4). In the case where a fetally expressed gene's expression is affected by the potential drug, prohibition of the drug to pregnant woman is indicated (col. 4, ln. 4-6). Similarly, a drug

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which causes expression of a gene which is not normally expressed by a fetus, should be prohibited to pregnant woman (i.e. measuring the expression of a female sample before drug treatment and comparing it to the expression profile of a sample from the same subject after drug treatment) (col. 4, ln. 6-9). The reference further teaches that monitoring of the efficacy of certain drugs can be accomplished by following the expression patterns of molecular markers (col. 4, ln. 20-23), and can be studied at various stages, such as gastrointestinal stages, at birth, postnatally, and throughout the human life cycle (col. 4, ln. 30-33).

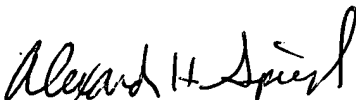
***Conclusion***

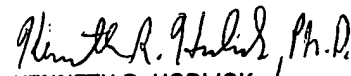
**6. No claims are allowable.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Alexander H. Spiegler  
May 4, 2001

  
KENNETH R. HORLICK, Ph.D.  
PRIMARY EXAMINER 5/4/01  
GROUP 1800/600